HedgePath Pharmaceuticals Closes Second Tranche of Mayne Pharma Financing
Additional $1.6 million in preferred stock and warrant funding to support SUBA BCCNS regulatory program HPPI to meet with FDA this month to discuss proposed 2018 NDA filing

FOR IMMEDIATE RELEASE -- TAMPA, FLORIDA (July 9, 2018) – HedgePath

Pharmaceuticals, Inc. (OTCQB:HPPI), a clinical stage biopharmaceutical company that discovers, develops and plans to commercialize innovative therapeutics for patients with cancer, announced that on July 5, 2018, it closed on a second tranche of funding from its majority stockholder, Mayne Pharma, as part of a securities purchase agreement executed in January 2018.

The $1.6 million in new funding will support HPPI's ongoing efforts with the U.S. Food and Drug Administration (FDA) toward the anticipated filing of a new drug application (NDA) with the FDA later in 2018 for its SUBA BCCNS clinical and regulatory program.

As with the initial funding tranche that closed in January 2018, HPPI issued shares of Series B preferred stock and warrants to purchase common stock to Mayne Pharma in the current funding. After giving effect to this most recent funding, Mayne Pharma owns 53.6% of HPPI's outstanding common stock and beneficially owns 59.1% of HPPI's voting securities (including shares of common stock, and shares of common stock underlying the Series B preferred stock and all warrants to purchase common stock held by Mayne Pharma).

HPPI will be eligible to receive a third tranche of $1.0 million on the same terms if its NDA for SUBA BCCNS is accepted by FDA by the end of this year (or in January 2019 if the NDA is filed in December 2018 and accepted within 30 days of filing).

Nicholas J. Virca, HPPI's President and Chief Executive Officer, stated "We are pleased to receive this additional capital, which takes our anticipated cash runway into the second quarter of 2019 and allows us to fully concentrate efforts on our SUBA BCCNS program. By way of update, on June 13, 2018, we filed a briefing package with FDA for our Phase 2(b) trial results in preparation for our face-to-face Type-C Meeting to occur with FDA on July 23, 2018. The July 23rd meeting is intended to provide us with further guidance regarding the regulatory pathway to potential approval of our SUBA-Itraconazole therapy for patients with BCCNS. We intend to provide updates when available through the remainder of the year as we proceed towards our anticipated NDA filing for SUBA BCCNS in 2018."

Readers are cautioned that no assurances can be given that the clinical study referenced herein will be found by FDA to be sufficient for an NDA filing, or if filed, that the NDA will be accepted and later approved by FDA.

About SUBA-Itraconazole

HPPI's lead drug candidate, SUBA-Itraconazole, is a patent-protected formulation of itraconazole, an approved oral antifungal drug that has been in use for over 25 years. HPPI is the exclusive U.S. licensee (through Mayne Pharma, the majority stockholder of HPPI) of SUBA-Itraconazole for the treatment of cancer. Prior to research at Johns Hopkins University, itraconazole was not known to have any target in mammalian cells. Investigators at Johns Hopkins discovered that itraconazole inhibits the hedgehog pathway by binding to a surface receptor in the pathway called Smoothened. Unlike generic itraconazole, that has poor and unpredictable bioavailability,

SUBA-Itraconazole can be dosed at half the level of the generic formulation due to its superior bioavailability, which exceeds 90%. As such, HPPI believes that generic itraconazole cannot be substituted for SUBAItraconazole.

About BCCNS

HPPI’s initial indication is for the orphan disease Basal Cell Carcinoma Nevus Syndrome, known as BCCNS. SUBA-Itraconazole has qualified under the FDA’s Orphan Drug Designation Program as a potential therapy for BCCNS.

There is no approved pharmaceutical therapy for this familial cancer syndrome. There are estimated to be 10,000 patients in the U.S. with BCCNS. This is an autosomal dominantly inherited defect in the hedgehog pathway that causes the pathway to be up-regulated, resulting in hundreds or even thousands of basal cell carcinomas developing over the lifetime of the affected patients. In many types of cancers, the hedgehog pathway is basically hijacked by the cancer cells to assist their growth and metastatic spread, but in the case of basal cell carcinomas, whether in this hereditary syndrome or in the much more common, sporadic basal cell carcinomas, the hedgehog pathway has a mutation that makes it the sole driver of the development of BCC tumors. Inhibition of the pathway, then, can inhibit the appearance of new tumors, shrink existing tumors, and even cause some tumors to disappear altogether.

Cautionary Note Regarding Forward Looking Statements

This press release and any statements of representatives and partners of HedgePath Pharmaceuticals, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the actual timing for, or actual results of, the Company’s clinical trial described herein, the Company’s meeting with FDA or the FDA’s review of any trial data or New Drug Application submitted by the Company to FDA as described herein) may differ significantly from those set forth or implied in the forward-looking statements (and may further differ from the Company’s previously announced interim study results). These forward-looking statements involve numerous risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forwardlooking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

For more information:

Nicholas J. Virca, President and CEO

nvirca@hedgepathpharma.com

Investor Relations Contact:

Garrison Hasara, CFO and Treasurer

ghasara@hedgepathpharma.com
